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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/076,267	02/14/2002	Vikas Kundra	UTSC:753US	3359

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BLAKELY SOKOLOFF TAYLOR & ZAFMAN
12400 WILSHIRE BOULEVARD
SEVENTH FLOOR
LOS ANGELES, CA 90025-1030

EXAMINER

KATCHEVES, KONSTANTINA T

ART UNIT PAPER NUMBER

1636

DATE MAILED: 07/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/076,267

Applicant(s)

KUNDRA, VIKAS

Examiner

Konstantina Katcheves

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 18-85 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-16 and 18-85 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-16, 18-36 and new claims 37-85 are pending in the present application. This Office action is mailed in response to the new and amended claims filed by Applicant in response to the Non-final rejection mailed 20 December 2002 and Applicant's Remarks to the Notice of Non-responsive Amendment, filed 22 April 2005.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-9, drawn to a fusion protein, classified in class 530, subclass 350.
- II. Claims 10-15, 37 and 66-69, drawn to drawn to a nucleic acid construct encoding a somatostatin receptor (SSTR) amino acid sequence wherein the encoding SSTR amino acid sequence comprises a carboxy-terminal truncation, expression vector comprising said sequence, and host cell comprising the expression vector, classified in class 435, subclass 320.1.
- III. Claims 16, 18-25, 38-65 and 78-85, drawn to a method of assaying for the detection of a recombinant seven transmembrane G-protein associated receptor, classified in class 435, subclass 6.
- IV. Claims 26-33, drawn to a DNA construct and method of assaying the ability of a mutant receptor to bind a ligand using said construct, classified in class 536, subclass 23.1.
- V. Claims 34-36, drawn to an imaging method detecting the expression of a fusion protein *in vivo*, classified in class 424, subclass 9.34.

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VI. Claims 70-77, drawn to a method for detecting cellular expression of a reporter, classified in class 435, subclass 6.

Inventions of Groups III, IV, V and VI are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The methods of Groups III-VI comprise steps which are not required for or present in the methods of the other groups: (a) introducing a nucleic acid encoding a recombinant seven transmembrane G-protein associated receptor into a host cell (Group III); (b) transfecting a cell with the DNA construct comprising a reporter protein and second polypeptide, quantization of expression and normalizing that quantity (Group IV); (c) detecting expression of somatostatin fusion protein *in vivo* (Group V); and (d) introducing a nucleic acid sequence encoding a reporter amino acid and/or leader sequence into a cell wherein the leader localizes the protein to a specific sub-cellular location (Group VI). The end result of the methods also differ: (a) detecting expression of a seven transmembrane G-protein associated receptor (Group III); (b) measuring the ability of a mutated receptor to bind a ligand (Group IV); (c) imaging of somatostatin *in vivo* (Group V); and (d) detecting cellular expression of a reporter amino acid (Group VI). Thus, the operation, function and effects of these different methods are different and distinct from each other. Moreover, the end results of each of these methods differ. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

Inventions of Group I, II and IV and Groups III, IV, V and VI are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The fusion protein product of Group I is not used in the methods of Groups III, IV, V and VI. The nucleic acid encoding construct encoding a somatostatin receptor (SSTR) amino

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acid sequence wherein the encoding SSTR amino acid sequence comprises a carboxy-terminal truncation, expression vector comprising said sequence, and host cell are not required for the methods of Groups III, IV, V and VI. The DNA constructs used in the method of assaying the ability of a mutant receptor to bind a ligand using said construct of Group IV is not required for the methods of Groups III, V and VI. The operation function and effects of each of these products differ completely from each other and are different and distinct from the operation function and effects of the methods of the above groups. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction

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requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined.

See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Because these inventions are distinct for the reasons given above and the search required for each of the Groups is not required for each of the others, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (571) 272-0768. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday 7:30 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Konstantina Katcheves
Examiner
Art Unit 1636



JAMES KETTER
PRIMARY EXAMINER